Eye, Organ, Tissue and Donor Designation Change Package for Hospitals- Partnering to Increase Donation

September 2009

Table of Contents

Overview

This document consolidates and updates the change packages from the Organ Donation and Transplantation Breakthrough Collaboratives conducted by the U.S. Department of Health and Human Services, Health Resources and Services Administration; Cornea Collaborative conducted by the Eye Bank Association of America, Donor Designation Collaborative conducted by Donate Life America; and Tissue Donation Collaborative conducted by AlloSource. This change package is created specifically for donor hospitals who are charged with assuring that eye, organ and tissue (E/O/T) donation happens successfully in the Nation's hospitals.

Representatives of the following organizations have partnered to create this consolidated change package to serve as a single point of reference for hospitals committed to honoring the donation intentions of patients and their families:

AlloSource
Donate Life America
Eye Bank Association of America
Organ Donation and Transplantation Alliance
U.S. Department of Health and Human Services, Health Resources and Services Administration.

Importantly, these change package concepts and actions have been used and significantly improved by the thousands of team members directly involved in testing changes and making improvements in E/O/T donation and donor designation. This is a "living document" that will continue to be improved over time.

The entire donation and transplantation community is indebted to all of those who have dedicated themselves to making changes and generating results, to saving and enhancing thousands of lives, and to providing compelling evidence that significant improvements in organ, tissue and eye donation and transplantation and donor designation can be achieved and sustained.

Guide to Using This Change Package

This document is organized into three sections:

- **Change Package Strategies, Change Concepts & Actions**
- **First Things First**
- **High Leverage Changes**

A comprehensive library of change concepts and action steps are provided for each of the strategies. These change concepts and action steps are listed in a table that allows teams to assess whether the hospital has, on its own or in partnership with the local organ procurement organization (OPO), tissue bank, eye bank or Donor Designation State Team, already tested the specific item – and if the hospital has implemented the concept or action. This will assist hospitals in identifying what improvements have already been put in place and which are yet to be tested, as a basis for continued improvement work.

Testing Changes and Making Improvements

In his landmark paper, "A Primer on Leading the Improvement of Systems"[1] Donald Berwick, MD, MPP, FRCP describes THE CENTRAL LAW OF IMPROVEMENT as follows:

"The relation derives from what I will call the central law of improvement: **every system is perfectly designed to achieve the results it achieves.** This aphorism encodes an understanding of systems that lies at the root of current approaches to making systems function better. The central law reframes performance from a matter of effort to a matter of design."

A corollary to this law is that:

"Not all change is improvement, but all improvement is change"

This change package, developed with the benefit of the collective experiential knowledge of high-performing leaders across the country, and continuously improved by thousands of front-line practitioners, reflects what we currently believe to be many of the best practices for

hospitals to increase organ, tissue and eye donation and transplantation and donor designation. It offers a vast selection of ideas you can rapidly test, using the Model for Improvement (for more information, see "A Primer on Leading the Improvement of Systems"[1]). Not every change you test will lead to improvement, but the only way to make improvements is to test changes. The intent of this change package is to provide you with actions to test, based on what has been proven to be effective elsewhere, and verified by others.

1) A Primer on Leading the Improvement of Systems, Donald M Berwick, MD, MPP, FRCP, President and Chief Executive Officer, Institute for Healthcare Improvement, Boston, MA 02215, USA. BMJ 1996; 312:619-622 (http://bmj.bmjjournals.com/cgi/content/full/312/7031/619)

Change Concepts & Actions

	Change Concepts & Actions	Date Tested	Date Implemented
1.	**Strategy: Unrelenting Focus on Change, Improvement, and Results** *Hospitals, in partnership with local procurement organizations, maintain a rigorous focus on and joint accountability for increasing the number of donors and donor designees by developing and maintaining a seasoned staff and creating a culture of excellence where honoring donor designation and donation is a priority.*		
1.01	**Establish strong culture of accountability for results: Orient operations towards outcomes rather than processes. Seek to improve each hospital's performance over its historical experience, using the Model for Improvement.**		
1.01a	Compare (benchmark) E/O/T donation and frequency of honoring donor designation performance to other hospitals in the donation service area (DSA), region and nation.		
1.01b	Create policies & guidelines that focus on measurable goals and standards for increasing opportunities for donation and honoring E/O/T donation intentions as well as improving authorization rates and establishing feedback for mutual critique and review.		
1.01c	Encourage hospital staff to know and talk performance benchmarks (authorization rates, conversion rates, timely notification rate, referral rate, transplant rates, and donor designation rates).		
1.01d	Assure that hospital staff know, regularly review and respond to data reports of E/O/T donation key indicators (authorization rates, conversion rates, timely notification rate, referral rate, transplant rates, donor designation rates).		
1.01e	Develop annual hospital specific needs assessment and action plans that identify and address barriers to improved E/O/T donation outcomes.		
1.02	**Apply 80/20 principle to focus resources; identify and target units with greatest E/O/T donation potential.**		
1.03	**Identify Performance Goals; measure, disseminate, and hold staff accountable.**		

1.03a	Use Week-in-Review meetings and monthly hospital reviews to dissect missed referrals, missed donor designations, "no authorizations" and "authorizations" as learning opportunities (analyze the failures as well as the successes).		
1.03b	Establish performance reviews for each staff member and/or unit to recognize individuals based on performance.		
1.04	**Provide Active Leadership and Management Support during donation and potential donation cases, to help Procurement staff overcome obstacles, plan re-approaches, address family needs and concerns, and to ensure consistency and quality in their vigorous pursuit of donation.**		
1.04a	Access and involve hospital and procurement organization leadership for effective staff support and oversight during donation cases in "real time".		
1.05	**Use data-driven decision making to determine priorities and effectiveness.**		
1.06	**Define and maintain relationships with key stakeholders, including procurement organizations, state based donor designation teams, medical examiners, coroners, transplant centers, and hospital physician leadership, and develop a seamless integration with hospital staff.**		
1.06a	Establish an effective working relationship between hospital CEO and senior leaders, procurement organizations and state based donor designation teams.		
1.07	**Support and encourage visual presence of procurement staff in hospitals so they become part of the fabric of the hospital in order to establish, maintain, and activate relationships with all individuals that participate in the donation process.**		
1.08	**Integrate public relations, communications plan & community activities to support statewide donor designation efforts.**		
1.08a	Design, implement, and monitor public education and outreach efforts to increase the frequency of donor designations in the hospital's local area.		
1.08b	Promote state registries and donor designations in the hospital and among hospital staff (i.e., all staff should be aware how to become a donor in the state).		

1.08c	Involve donor families and transplant recipients to raise awareness and provide opportunities to advance discussions of E/O/T donation and increase donor designations.		
1.08d	Target public outreach efforts to increase donor designation and education to the communities and ethnicities served by the hospital.		
1.08e	Never lose an opportunity to make a positive, lasting, and communicable impression on donor families and others in the community through public service announcements, media events, news articles, etc.		
1.09	**<u>Provide timely hospital/clinical leadership specific feedback</u> on all areas of performance on E/O/T donation and transplantation.**		
2.	**Strategy: Rapid, Early Referral & Linkage** *Key hospital and procurement organization staffs are linked in a timely manner to potential donor families.*		
2.01	**<u>Establish a system-wide commitment</u> to unconditionally identify all opportunities for donation and honor donor designation. Collaboratively control effective authorization request steps. Hospital and procurement organizations communicate early – for E/O/T donation before death is pronounced - in order to jointly develop an approach plan. Establish protocols jointly between hospital and procurement staff to ensure timely identification and referral of potential donors.**		
2.01a	Tailor or adapt the E/O/T donation process to complementary strengths of hospital and procurement organizations.		
2.01b	Work as a team with procurement staff to determine the existence of a donor designation and the right person(s) to initiate the donation conversation in the absence of a designation. Establish family communication plan that incorporates all members of patient care team.		
2.01c	Teach hospital staff clinical triggers for referrals that are mutually agreed upon by the hospital and the procurement organization.		
2.01d	Have “go to” persons who are champions for E/O/T donation and donor designation on hospital units with high donor potential.		

2.01e	Fly the Donate Life Flag during the month of April in prominent hospital areas to encourage donor designations.		
2.01f	Create a special recognition such as flying the Donate Life Flag whenever a there is a donor at the hospital.		
2.02	**<u>Establish customized protocols for E/O/T donation</u> to standardize the use honoring of donor designations or approaches to families and assure that all have a positive experience regardless of their decision. In the absence of donor designation, systematically make every effort to determine a family's willingness to donate, and recognize that re-approach may be necessary.**		
2.02a	Identify the family support system in the hospital (social work, chaplains, etc.) and link these resources with procurement organizations at first point of contact between the hospital and the procurement organization.		
2.02b	Start early to understand family dynamics, identify key decision-maker(s), monitor status, and support family needs.		
2.02c	Provide appropriate information and instruction on determination of death to families, preferably in writing.		
2.02d	Factor in spiritual and cultural needs of each family; train hospital staff and procurement staff to increase cultural awareness. Prepare to adapt to particular family needs or requests to facilitate E/O/T donation.		
2.02e	Match requesters appropriately to family, ensuring effective requesters are available; special requesters should be hired and utilized by the hospital and/or procurement organization specific to the ethnicity of the hospital service area population.		
2.02f	If procurement staff is not making the request, partner with the procurement organization to establish a designated requester program with training that emphasizes success measured by numbers of families who provide donation authorization.		
2.02g	Nurses, social workers, hospital-based pastoral care staff may be used as certified organ/tissue requesters as agreed upon by hospital and procurement organization staff.		
2.02h	Closely monitor authorization rates, provide feedback to donation units on their rates of success and		

	make changes as indicated by performance.		
2.03	**<u>Develop specialized roles</u> keyed to specific skills needed throughout donation process: clinical/technical experience in critical care or trauma settings; family therapy or counseling/social work; business development/marketing.**		
2.03a	Consider partnering with procurement organizations to employ an in-hospital coordinator with Hospital Development responsibility to establish early interaction with family and provide consistent day-to-day management of the E/O/T donation system within the facility.		
2.04	**<u>Pro-actively establish relationships</u> between hospital and procurement organization staff to include: key patient care, nursing and medical leadership, family support staff, and administration.**		
2.04a	Clarify respective roles of hospital and procurement personnel in the donation process continuum and educate both regarding complementary roles.		
2.04b	Dispel the many myths surrounding E/O/T donation and donor designation for both families and staff.		
2.04c	Establish a defined family liaison role within hospital – use family counselors/specialists as requesters as needed.		
3.	**Strategy: Integrated Donation Process Management** *Hospitals and procurement organizations establish and manage an integrated donation process that clearly defines roles and responsibilities and provides feedback.*		
3.01	**<u>Establish joint hospital and procurement organization(s) designated leadership responsibility and accountability</u>. Procurement organization(s) provides resources for all donation-related matters; Hospital provides high level support with procurement organization(s) input (at a minimum, CMO, VP level).**		
3.01a	Develop action plan to assure respective roles are known and understood by procurement organization(s) and hospital leadership and staff.		
3.01b	Create expectation that procurement organization(s) takes responsibility for meeting and maintaining hospital CMS regulations requirements by establishing policy defining imminent death, assuring timely		

	referral, providing education and continual feedback.		
3.01c	Create expectation that the procurement organizations uphold the Uniform Anatomical Gift Act, if appropriate in donor hospital. To see if state has enacted law go to: http://www.anatomicalgiftact.org		
3.01d	Establish hospital-specific E/O/T donation committee(s) with representation from all relevant staff including, but not limited to, physicians, nurses, hospital administrative leadership, and family support services (social workers, chaplains) to review monthly potential donor data and cases, and address CQI. Ensure strong leadership, hospital sponsorship, and significant critical care, procurement organization and state-based donor designation team representation.		
3.02	**<u>Utilize appropriate data and tools</u> to provide immediate feedback to hospitals/clinical leadership on donation process/results/outcomes with specific follow-up requests and action steps.**		
3.02a	Use death record reviews to establish referral, authorization and donation rates, and automate process in order to monitor performance in real time.		
3.02b	Maintain a formal process for comprehensive immediate follow-up between procurement organization(s) and hospital on every E/O/T donor referral regardless of the outcome (after action review); system to include guidelines for in-person follow-up, debriefing and mutual critique of process as well as written correspondence and email communication to facilitate timely feedback where access is difficult.		
3.03	**<u>Build and maintain collaborative relationships</u> between key hospital staff/physicians, procurement organizations, and state-based donor designation teams at all levels that impact the donation process.**		
3.03a	Identify and support E/O/T donation champions at various hospital levels; include leaders who are willing to be called upon to overcome barriers to donation in real time.		
3.04	**<u>Partner, consult with, and provide curriculum to clinical leadership</u> (physicians and nurses) to establish declaration of death policy, documentation and guidelines for declaration of death discussion with family. Establish standards for stabilization of potential donors.**		
3.05	**<u>Educate appropriate hospital staff/physicians</u> by providing physician and staff in-services at regular sessions to create and maintain procurement organization(s) responsibilities, appropriate awareness, and understanding of policies.**		

3.05a	Provide hospital unit-based education and target core curriculum/education to referring staff: donor advocacy, bereavement care, certified (designated) requesters, etc.		
3.06	**Use survey tools to evaluate/monitor donation process, identifying trends/strengths/problems.**		
3.06a	Utilization of data gathered during donation process to identify opportunities for improvement.		
3.07	**In order to maximize better E/O/T recovery, jointly establish expectations, guidelines and protocols between procurement organization(s) and hospital departments required by each type of donation.**		
3.07a	Create and utilize standardized mechanisms for feedback, collaboratively identify action steps, if needed, and monitor progress.		
4.	**Strategy: Aggressive Pursuit of Every Donation Opportunity** *Every possibility for increased donation is maximized and routinely evaluated through death record reviews, evaluation of donation benchmarks, frequency of honoring donor designation, re-approach, donor management and improved yield.*		
4.01	**Constantly look for, evaluate, and address every donor potential. Advocate for donation.**		
4.01a	Use 100% death record reviews (DRR) and report of death forms to identify missed opportunities, follow-up appropriately with involved staff, and identify and test indicated changes to prevent recurrence.		
4.01b	Establish hospital policies and procedures to assure 1) timely notification of all brain injured patients with a Glasgow Scale (GCS) of 5 or less, and 2) maintenance of physiologic function until the procurement organization(s) has determined suitability and families are offered the option of donation.		
401c	Establish a mutually agreed upon on-site response time by procurement agency coordinator or designee to every appropriate referral, such as within one hour.		
4.01d	Assess and re-evaluate reasons family has declined donation and consider re-approaching if appropriate.		
4.02	**Develop, define, and maintain a standard of high quality service in handling all communications**		

	between hospital staff and procurement organizations.		
4.03	**Establish, evaluate and be accountable for a clear donor management process from referral to recovery with procurement agency oversight from the procurement directors and/or medical director(s).**		
4.03a	Integrate critical care professionals into organ donation process; assure an intensivist is involved in appropriate organ donation opportunities.		
4.04	**Increase the interaction between OPO medical director and hospital physicians by identifying physician champions and establishing QI/QA processes with physicians through one-on-one case reviews and education.**		
4.05	**Hospital and procurement organizations partner with medical examiners/coroners to establish expectation of no (zero) denials .**		
4.05a	Immediately address ME/coroner denials with procurement organization leadership (medical and administrative) at the time of occurrence. Consider advocating legislation (see Sec. 4.11.a, HHS Secretary's Advisory Committee on Organ Transplantation. Recommendation #10 states that legislative strategies be adopted that will encourage medical examiners and coroners not to withhold life-saving E/O/Ts from qualified procurement organizations).		
4.06	**Coordinate Do Not Resuscitate (DNR) and Comfort Measures Only (CMO) planning process between hospital and procurement organization staff to avoid conflict with the opportunity for E/O/T donation.**		
4.06a	Establish hospital protocols that include a provision for maintaining hemodynamic support for potential donors, inclusive of cases where family has requested a DNR order without knowledge of donation options.		
4.06b	Conduct joint training sessions for hospitals and procurement organizations on authorization, communications, and discussions surrounding end-of-life decision making. Sessions will include skills, practice, and role-playing.		
4.06c	Educate hospital and procurement organization staff regarding impact of DNR/CMO status on the potential for E/O/T donation.		

4.07	**<u>Establish procurement organization and hospital policies and protocols for donation after cardiac death (DCD)</u> to ensure the referral of all patients with non-recoverable neurological injuries and pursuit of donation options.**		
4.07a	Introduce and implement sample policies and procedures based on the Institute of Medicine (IOM) recommendations.		
4.07b	Integrate DCD routinely into all hospital staff education; develop hospital staff training program to include review of the literature, IOM recommendations, discussion of ethical considerations, case review, and clinical procedures.		
4.07c	Clarify legal hospital specific authorization procedure and forms for DCD.		
4.07d	Aggressively pursue each opportunity for DCD in the instances where it is clinically reasonable and there are documented donation intentions or the family wishes to donate regardless of policy status. On a regular basis, measure and report DCD activity within the hospital.		
4.08	**Embody an attitude that honoring and fulfilling eye and tissue donation intentions is equally important to organ donation.**		

5.	**Strategy: Intent - A culture of accountability for high yield (8 organs, tissue and eyes every time)** *There is clear intent to maximize the number of organs, tissue, and eyes transplanted. It is expressed and tracked as a mission: every donor, every organ, every tissue, every time. Actions and interactions among donor hospital, procurement organizations, and transplant program staff demonstrate that everyone is committed to the mission. There is rigorous use of goals benchmarked with national best practice that are routinely reviewed for performance.*		
5.1	**<u>Walk the Talk</u>: Create a common culture within the hospital, procurement organizations, and transplant programs in which all participants "walk the talk" the mission of achieving high procurement and transplant rates.**		
5.1a	Share E/O/T outcomes and frequency of honoring donor designation among hospital personnel.		
5.1b	Consistently recognize and commend outstanding achievements in E/O/T procurement in the hospital.		

5.1c	Partner with donor families, transplant candidates, and transplant recipients to motivate improvement and recognize successes in increasing E/O/T procurement and utilization.		
5.1d	Benchmark hospital utilization rates (such as organs transplanted per donor or OTPD) to local, regional and national performance leaders.		
5.1e	Develop and collect a "dashboard" of indicators on donation, donor designation, transplantation, and other key parameters to reflect hospital performance.		
5.1f	Integrate donation into the mission statement of the organization.		
5.1g	Integrate honoring donor designation into the goals of the organization.		
5.2	**<u>Eight + Tissue is Great</u>: Refer and evaluate every potential donor every time, approaching each donor as an 8 organ, 2 cornea and maximum tissue donor.**		
5.2a	Utilize the timely notification and effective request best practices relevant to E/O/T donation.		
5.2b	Systematically implement DCD policies and procedures in the hospital.		
5.2c	Establish clear referral criteria and procedures that promote timely notification and capture a wide range of potential donors, including ECD (Expanded Criteria Donor) and DCD donors and tissue and eye donors.		
5.2d	Utilize donor designations and, in the absence of documentation of donor's wishes, support donor family deliberations and decisions with information about the impact of donating all 8 organs along with eye and tissue.		
5.2e	Utilize procurement agency and/or hospital effective requesters in every case.		
5.2f	For Standard Criteria Donor (SCD) and DCD cases, routinely obtain donation authorization for all organs and tissues, including eyes. For tissue only cases, obtain authorization for all tissues, including eyes.		
5.2g	Test and implement improvements to the donation authorization process and practices using after action reviews.		

5.2h	Utilize re-approach strategies when authorization for all 8 organs, eye, and tissue is not obtained. Identify and address the family's reasons for restricting authorization.		
5.4	**<u>Empowering Infrastructure</u>: Develop effective governance structures across the donation system to support high E/O/T utilization and frequency of donor designation.**		
5.4a	Participate in donor-specific procurement organization committees to develop policies and evidence-based clinical protocols to support high E/O/T utilization.		
5.4b	Support hospital clinicians to participate on procurement organization boards and committees to advocate for all organ types.		
5.4c	Implement donor referral system that encourages timely notification of all ventilator dependent patients with non-recoverable neurological injuries or when "Do Not Resuscitate" decisions are being made.		
5.5	**<u>Improvement Driven</u>: Practice accountability for high E/O/T utilization as a continuous learning and quality improvement process.**		
5.5a	Systematically capture and make use of data across the continuum from frequency of honoring donor designation to pre-donor management.		
5.5b	Identify and support a champion at the hospital to ground the work of the team in the Model for Improvement. (www.ihi.org)		
5.5c	Incorporate E/O/T utilization and frequency of honoring donor designation into hospital QAPI data.		
5.6	**<u>Hitting Bold Targets</u>: Establish bold organ-specific recovery and donor designation goals and practice organ specific accountability for high organ utilization.**		
5.6a	Partner with procurement organizations to regularly monitor and report E/O/T specific utilization data to donor hospital leaders.		
5.6b	Partner with procurement organizations to develop E/O/T-specific targets (stretch goals) to generate increases in recovery and transplantation rates.		
5.6c	Partner with procurement organizations to create a dashboard report with clinical indicators for E/O/T		

	utilization rates including reasons why E/O/Ts are not recovered and transplanted. Share performance benchmarks with other hospitals to foster DSA-wide improvement.		
5.6d	Incorporate E/O/T utilization and donor designation data into hospital QAPI data.		
6	**Strategy: Effective Relationships - A rapid response network responsible for donor management, organ recovery, and placement.** *Build and sustain a network of quick response, collaborative relationships with donor families, hospital staff, E/O/T procurement organization staff, state-based donor designation teams, transplant physicians and surgeons, and transplant program staff. Necessary and sufficient skilled hospital, E/O/T procurement organization and transplant program staff are in place and ready to respond. Policies, processes and communication channels with partners are well defined, practiced, and monitored. Deep relationships assure timely and correct responses that promote high E/O/T transplantation rates.*		
6.1	**Cultivating Commitment: Cultivate a commitment in each unit involved to achieve high E/O/T donation and transplantation rates.**		
6.1a	Participate in DSA E/O/T specific committees including transplantation, critical care, and procurement experts to review and discuss local protocols in light of national recommendations such as the Crystal City Consensus Conference and other E/O/T standard setting documents.		
6.1b	Dedicate efforts to cultivate and maintain hospital commitment to achieving high rate of E/O/T utilization and honoring donor designation.		
6.1c	Provide positive feedback to hospital unit staff about how their efforts have affected the lives of E/O/T transplant candidates.		
6.1d	Learn about and incorporate the needs of transplant programs and help to build relationships and communication links among procurement organization, hospital, and transplant program personnel.		
6.1e	Partner with procurement organization(s) to conduct outreach to medical examiners/coroners prospectively and during donor cases to accommodate any potential forensic investigations.		
6.2	**Focused, Integrated Estates: Actively participate in achieving seamless integration among the procurement organizations, donor hospital, and transplant program to achieve a high transplantation rate.**		

6.2a	Create network among procurement organization(s), hospital, and transplant programs to identify specialists (cardiology, pulmonology, etc) essential to donor evaluation.		
6.2b	Build relationships with first-responders (police, fire, ambulance) and first-receivers (emergency department staff) to increase awareness of potential donors.		
6.2c	Designate hospital space with a telephone and fax machine for use by procurement organization during donor cases.		
6.2d	Encourage procurement organization presence into the institutional functions of high volume donor hospitals.		
6.2e	Create an environment where procurement organizations can provide expertise, services, and support to reduce hospital burden for donor management and recovery.		
6.2f	Enable procurement organizations, hospital administrators, and transplant programs to respond in real-time when resources and/or support is required during donor cases.		
6.2g	Designate an ICU bay staffed by "E/O/T donor nurse experts" or prioritize donor cases for the OR.		
6.3	**<u>Triple Thread</u>: Using leading practices of procurement organizations, hospitals, and transplant programs build policies, processes and communications to mobilize resources and timely participation.**		
6.3a	Utilize cerebral perfusion scan to facilitate timely death pronouncement.		
6.3b	Partner with procurement organization(s) to establish internal notification trigger to alert hospital physicians/specialists and ancillary departments necessary to implement donor evaluation and management.		
6.3c	Develop evidence-based practices that facilitate maximum E/O/T utilization.		
6.3d	Establish multi-disciplinary teams to test and implement effective changes.		
6.3e	Treat increasing E/O/T transplanted per donor as an area of unrealized potential for narrowing the gap between the demand and supply of E/O/Ts.		

6.3f	Identify and empower a model for improvement champion on the high donation units to structure performance improvement processes.		
6.3g	Partner with procurement organizations to identify areas within procurement organizations, hospital or transplant programs to build capacity to carry out donor management, organ placement and organ recovery processes such as building in-house OR or lab or investing in technology to place all viable E/O/T(s).		
6.4	**<u>Ready, Rapid Resources</u>: Organize to deploy the necessary level of hospital expertise in rapid, real-time fashion.**		
6.4a	Standardize core competencies for critical care staff in regards to E/O/T donation and designation.		
6.4b	Provide real-time experienced senior resource staff from procurement organizations, hospital, and transplant programs to assist front-line staff to implement the donation process and honor donor designation (family approach, donor evaluation, donor management, organ placement, E/O/T recovery).		
6.5	**<u>Real Time Check-In to Rule In</u>: Organize for effective procurement organization, hospital, and transplant program decision-making throughout the entire donation process.**		
6.5a	Partner with procurement organization(s) to devise a multi-level decision process (medical director, administrator on call, local, regional or national experts) to rule in all possible potential E/O/T donor cases.		
6.6	**<u>Motivating Results</u>: Nurture procurement organization, hospital, transplant program, and state-based donor designation team relationships with compelling data showing results on the mission.**		
6.6a	Schedule after action reviews with key procurement organization, hospital, and transplant program staff to assess donor management, E/O/T utilization, and transplant outcomes.		
6.6b	Facilitate ongoing interactions among procurement staff, hospital physicians, and transplant physicians/surgeons.		
6.6c	Combine statistical feedback with compelling recipient outcomes/testimonies.		

6.6d	Celebrate and honor hospital (specific units) contributions to increasing E/O/T utilization.		
6.7	Embody an attitude that all types of donation are of equal importance to donor families.		
6.8	Fulfill role of being the driver of utilizing donor designation.		
6.9	Support state registry by offering donor designation opportunities in the hospital and the local community.		
6.9a	Participate in the Workplace Partnership for Life program.		
7	**Strategy: Advanced Practice - Accountability for aggressive clinical care of the potential donor, the donor, and all eyes, organs and tissues.** *Practice continuity of aggressive clinical care for all E/O/Ts from timely referral, through brain death declaration, to recovery. Access and use advanced clinical practice support and best practices. Recognize the physiology of brain death and incipient herniation and implement standardized approaches to the declaration of death, obtaining donation authorization, and medically managing the donor. Optimal management ensures that the donor somatically survives to procurement and that the E/O/Ts are maintained in optimal condition leading to higher utilization rates.*		
7.1	**<u>More Time, More Organs, Tissues and Eyes</u>: Timely referral by hospital with more powerful communication among procurement organization staff, attending physicians, and nurses.**		
7.1a	Implement clinical triggers and track compliance.		
7.1b	Implement DCD protocols.		
7.1c	Establish a DCD champion within the hospital to promote implementation.		
7.2	**<u>Intensive Patient Care</u>: Stress and maintain continuity of aggressive intensive clinical care throughout brain death declaration process.**		
7.2a	Implement a standardized brain death declaration protocol that achieves timely declarations.		
7.2b	Utilize confirmatory studies such as cerebral blood flow study to minimize waiting time between clinical examinations.		
7.2c	Establish patient management protocols that preserve organ function as well as eye and tissue integrity		

	without compromising neurologic status prior to pronouncement of death.		
7.3	**<u>Optimize Organ Systems</u>: Stress and maintain aggressive clinical management of all donor organ systems and preservation of eye and tissue integrity.**		
7.3a	Conduct an organized pre-donor briefing or "team huddle" (all stakeholders agree on goals, solutions to potential problems, care plan) in every case.		
7.3b	Implement donor management protocols that optimize care across all E/O/T systems without compromising one organ/tissue for the sake of another.		
7.3c	Involve senior clinical OPO staff in collaboration with hospital physicians and transplant clinicians in donor management.		
7.3d	Implement donor management and E/O/T recovery protocols with input from transplant and critical care experts that are specific to organ, donor (SCD, ECD, DCD, pediatric) type and eye and tissue type and are consistent with cutting edge practice.		
7.3e	Conduct a thorough review evaluation of all 8 organs and all transplantable tissues including eyes regardless of age, medical history, donor type or health status.		
7.3f	Continually re-evaluate the status of all 8 organs and tissues including eyes throughout the donor management process. Re-invigorate organ placement efforts if clinical status improves.		
7.3g	Maintain early and ongoing communication with the operating room and anesthesiology to enable clinically optimal E/O/T recovery.		
7.3h	Perform organ recovery when the donor has been stabilized, maximize number of organs that are viable, maximize number of organs have been placed, rather than as soon as a few recovery teams or transplant surgeons are ready. Perform eye and tissue recovery according to recovery protocols.		
7.3i	Conduct after action reviews including procurement organizations, hospital, and transplant program staff to identify what worked, why it worked, and what to do more of, better, or differently in future cases.		
7.4	**<u>Team Expertise</u>: Identify, organize, and utilize advanced clinical practice expertise.**		

7.4a	Seek early and active consultation with pulmonary/critical care physicians for all donors.		
7.4b	Provide prompt follow-up information (including opportunities for clinical improvement) to clinicians involved in the donor care process.		
7.4c	Establish and maintain continuity of intensivist involvement in donor management in the peri- and post pronouncement of death time period (in consultant role) – joint OPO/intensivist involvement.		
7.4d	Implement an evidence-based donor critical pathway and track involvement.		
7.4e	Partner with procurement organizations to provide extensive clinical education to hospital staff including ongoing booster education sessions.		
7.4f	Perform literature searches to present cases of ECD or DCD organs that have been transplanted successfully.		
7.5	**<u>Utilize Donor Champions</u>: Identify and deploy advanced practice practitioner for advanced clinical donor management and aggressive organ acceptance.**		
7.5a	Partner with procurement organization to utilize advanced practice clinical staff (NP/PA/other) for challenging cases.		
7.5b	Structure staffing models to provide on-site, skilled support to the authorization process, donor management and E/O/T placement efforts.		
7.5c	Assemble a cadre of consultants who are available to offer expert advice when needed.		
7.5d	Assign OPO and/or hospital staff with critical care experience to manage the care of organ donors.		
7.5e	Partner with procurement organization to help develop advanced practitioners that are able to perform donor management procedures typically performed by physicians or other advanced clinicians.		
7.5f	Partner with advanced clinical staff who can supervise donor management efforts 24/7.		
7.5g	Formally designate a hospital physician as “organ donor management expert” with defined role in the donor process.		
7.5h	Use clinical procedures such as extracorporeal membrane oxygenation (ECMO), pulsatile preservation		

	(pump) or restructure care (move DCD cases close to OR prior to withdrawal of life support) to minimize the effects of warm and cold ischemic time on E/O/T recovery.		
7.5i	Partner transplant surgeons with critical care physicians who are familiar with state-of-the-art and emerging transplantation techniques and have experience with ECD and DCD organs.		
7.6	**<u>Maximize Successful Recovery</u>: Implement and ensure timely and well-organized advanced clinical recovery practices.**		
7.6a	Enable withdrawal of life-support in OR or other designated area for DCD cases.		
7.6b	Conduct pre-recovery briefings for OR staff in partnership with procurement organizations.		
7.6c	Customize and adapt operating rooms and instruments to recovery team needs.		
7.6d	Document family contact information.		
7.6e	Establish protocol for proper eye care.		
7.6f	Timely transport of deceased donor to appropriate area of hospital for tissue and eye recovery.		
7.6g	Deploy highly skilled teams to participate in the organ procurement procedure.		

Centers for Medicare and Medicaid Resources:
State Operations Manual Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals see:

- §482.45(a)(1) – (5))- http://www.cms.hhs.gov/manuals/Downloads/som107ap_a_hospitals.pdf
- § 482.45 Conditions of participation: Organ, tissue, and eye procurement- http://edocket.access.gpo.gov/cfr_2004/octqtr/pdf/42cfr482.45.pdf

The Joint Commission Resources:
Revisions to Standard TS.01.01.01, EP 9 – Applicable to Critical Access Hospitals and Hospitals- http://www.jcrinc.com/common/PDFs/fpdfs/pubs/pdfs/JCReqs/JCP-03-09-S6.pdf

First Things First

Building blocks that need to be in place to create a redesigned E/O/T donation system. These are the basics, the key change concepts and action items that teams need to do first.

		Team Assessment of 1st Things 1st	
		Yes	**No**
1	**Physician and clinical champions are known.**		
2	**Process in place for real-time Death Record Review.**		
3	**Procurement Organization(s) "presence": In House Coordinator(s).**		
4	**Focused Change Agenda based on analysis of current hospital data.**		
5	**"Team Huddles" are the norm.**		
6	**Clinical Triggers are in use.**		
7	**After Action Reviews are the norm.**		
8	**"Effective Requesting" in place and in action.**		

High Leverage Changes

The framework for a redesigned E/O/T donation system.

		Team Assessment of HLC	
		Yes – Currently In Place or In Action	**No – Improvement Still Needed**
1	**Advocate E/O/T Donation and Donor Designation as the mission.**		
2	**Involve senior leadership to get results.**		
3	**Deploy a self-organizing Procurement Organization(s)/Hospital Team.**		
4	**Practice Timely Referral.**		
5	**Master Effective Requesting.**		
6	**Implement Donation after Cardiac Death.**		

High Leverage Transplant Practices

The high leverage transplant practices (HLTP) create the framework for the redesigned system to achieve the collaborative goals. HLTP's have a direct relationship to outcomes and results. They are often a synergistic combination of change concepts within strategies, incorporate all 3 estates, and reflect current practices of our high performing teams. Increasing the overall number of E/O/T(s) transplanted is a direct result of an intensive focus on the HLTP's.

		Team Assessment of HLC	
		Yes – Currently In Place or In Action	**No – Improvement Still Needed**
1	**Efficiently plan and manage the donor case process, taking the appropriate amount of time.**		
	Establish an effective system to optimize organ function and placement efforts, especially thoracic organs.		
	Collaboratively develop an organ offer process to address transplant center notification/timing.		
	Procurement Organizations, Transplant Program and Donor hospitals view themselves as part of a mutually accountable team.		
2	**Involve critical care specialists to maximize donor management.**		
	Create joint accountability for increasing organ transplantation with these valuable expert partners.		
	Treat every donor like a lung donor.		
	Develop donor management guidelines based on leading clinical practices.		
	Set and track donor management goals.		
	Put a system in place so hospital clinical specialists stay engaged throughout the donor case		
3	**Relentlessly advocate for the placement of every transplantable E/O/T.**		
	Ensure all appropriate clinical and administrative expertise is available for each case.		
	Evaluate donor case process performance and E/O/T outcomes every time.		
	Systematically track, evaluate and maximize the outcomes, especially for DCD and ECD		

	organs.		
	Data and dashboards on performance are routinely reviewed and exchanged among organizations.		

Improvement Glossary

Term	Definition
Action Period	The period of time between Collaborative Learning Sessions when spread teams work within their organization to meet their spread goals. Participants focus on the spread of ideas and processes within their own organization during this period while staying in continuous contact with other participants and faculty.
Actionable Item	A specific idea or suggestion that can be tested and implemented to improve a process.
Aim	An aim for spread is an explicit statement summarizing what the organization seeks to achieve in its spread effort. It is the responsibility of executive leaders to ensure that the spread aim is aligned with the strategic goals of the organization.
Annotated Time Series	A line chart showing results of improvement efforts plotted over time. The changes made are also noted on the line chart at the time they occur. This allows the viewer to connect changes made with specific results.
Assessment Scale	A numerical scale used to assess the progress of participating teams toward reaching their aim. Spread Leaders are asked to assess their own progress using the scale as well.
Change Concept	A general idea for changing a process. Change concepts are usually at a high level of abstraction, but evoke multiple ideas for specific processes. ("Establish strong culture of accountability for results, use data-driven decision making to determine priorities, and create and maintain visual presence of procurement organization staff in donor hospitals," are all examples of change concepts.)
Change Package	The key content for the Collaborative which provides a listing of the essential changes needed to get results. The change package includes ideas that are supported by evidence in the literature or from credible expert opinion.
Clinical Triggers	Criteria for "imminent death" mutually established by the hospital and OPO which prompt the hospital to make a timely notification to the OPO.
Collaborative	A time-limited effort (usually 6 to 12 months) of multiple organizations that come together with faculty to learn about and to create improved processes in a specific topic area. The expectation is that the teams share expertise and data with each other, thus "everyone learns, everyone teaches".

Collaborative Site	The location for initial focused changes. After implementation and refinement of changes in this site, the ideas and/or processes are spread to additional locations.
DCD	Donation after Cardiac Death
Early Adopter	In the improvement process, the opinion leader within the organization who is willing to try new ideas (introduced by innovators) and whose positive results attract others in the organization to adopt the successful changes [Rogers E. Diffusion of Innovations. 4th ed. New York, N.Y.: The Free Press; 1995. Note: Importance of change agents; agenda setting in organizations]
Expanded Criteria Donor (ECD)	Donors after brain death (DBD) meeting the OPTN expanded criteria definition OPTN expanded criteria definition 1. Organ donors over the age of 60 years or organ donors 50-59 years with 2 of the following 3 co-morbidities: CVA as cause of death; history of hypertension at any time; creatinine greater than 1.5 mg/dl
Early Majority/Late Majority:	The individuals in the organization who will adopt a change only after it is tested by an early adopter (early majority) or after the majority of the organization is already using the change (late majority) [Rogers E. Diffusion of Innovations. 4th ed. New York, N.Y.: The Free Press; 1995. Note: Importance of change agents; agenda setting in organizations]
Effective Request Process	A process developed collaboratively between the hospital and the procurement organization that culminates in the request to the family using tested and proven methodology.
Executive Leader	The executive leader ensures that the spread aim is aligned with the strategic goals of the organization and is responsible for assigning senior level and day-to-day leadership for spread.
First Things First	What Successful Teams Have Tackled First to Assure That Change is Deep Enough into the System to be Sustained: • Create Procurement Organization Hospital Presence/In House Coordinator • Analyze and Apply Current Hospital Specific Data • Identify Physician/Clinician Champions • Conduct Real Time Death Record Reviews • Establish Clinical Triggers • Hold Donation Team Huddles • Identify and Utilize Effective Requesters in Every Case • Conduct After Action Reviews

High Leverage Changes	High Leverage Changes Have a Direct Relationship to Outcomes/Results and are a Combination of Change Package Concepts. Six actions to create a high performance, organ donation system: 1. Advocate E/O/T Donation As The Mission 2. Involve Senior Leadership To Get Results 3. Deploy A Self-Organizing Procurement Organization/Hospital Team 4. Practice Early Referral, Rapid Response 5. Master Effective Requesting 6. Implement Donation After Cardiac Death
Huddle	A structured multi-disciplinary meeting of hospital and procurement organization staff used to coordinate the Effective Request Process and to meet the unique needs of each eligible donor's family.
Ideas	Concepts on which to base the design of a new system. Since new aims require changes of systems it is important to identify promising changes and to avoid useless ones.
Implementation	Taking a change and making it a permanent part of the system. A change may be tested first and then implemented throughout the organization.
Improvement Leader	The Improvement Leader organizes and drives the spread project in their donation service area.
Innovator	In the improvement process, the person(s) who goes outside the organization to find new ideas. This person may not be well connected to others in the social system [Rogers E. Diffusion of Innovations. 4th ed. New York, N.Y.: The Free Press; 1995. Note: Importance of change agents; agenda setting in organizations]
IS	Refers to the Information System in the organization, usually the computerized information system.
Learning Session	An intensive two day meeting designed to focus on a set of key components to support effective spread, build learning relationships with other day-to-day spread agents, and support participants in making plans for their organization's spread work.
Measure	An indicator of change. Measures for spread are focused on the rate of spread and key outcomes measures related to the performance of the system.
Measurement Strategy	The key measures that will be used to track improvement in the Collaborative. The measurement strategy contains process and outcome measures and definitions of the data elements.
Model for Improvement	An approach to process improvement, developed by Associates in Process Improvement,

	which helps teams accelerate the adoption of proven and effective changes.
OPO	Organ Procurement Organization
PDSA	A structured trial of a process change. Drawn from the Shewhart Cycle, this effort includes: • PLAN – a specific planning phase • DO – a time to try the change and observe what happens • STUDY – an analysis of the results of the trial • ACT – devising next steps based on the analysis The Plan, Do, Study, Act Cycle describes inductive learning – the growth of knowledge occurs through making changes and then reflecting on the consequences of those changes. The Model for Improvement intends that the enterprise of testing change in informative cycles should be part of normal daily activity throughout an organization. To be a PDSA cycle the test or observation was PLANNED; the plan was attempted (DO); time was set aside to analyze the data and STUDY results; and ACTion was rationally based on what was learned.
Prework Packet	A document containing a complete description of the Initiative, along with expectations and activities to complete prior to the first Learning Session of the Initiative.
Prework Period	The time prior to the first Learning Session when teams prepare for their work in the Spread Initiative, including designating both a senior leader and a day-to-day spread agent, establishing a team, developing preliminary aims and measures and summarizing work in progress in a storyboard.
Process Change	A specific change in a process in the organization. More focused and detailed than a change concept, a process change describes what specific changes should occur. "Use Week-in-Review Meetings and monthly hospital reviews to dissect missed referrals".
Pull	This is a strategy in the OTBC Change Package where transplant programs work to optimize organ acceptance and success rates for each organ type. The purposes of the Pull Strategy are to: • Evolve an effective game plan for accepting all organs; • Understand and guide the capacity to transplant more organs in the DSA; • Maximize the likelihood of patients having a successful transplant rather than dying on the waiting list; • Assure transplant program practice is as aggressive as possible; and, • Create relationships with OPOs in other DSAs to assure the capacity to receive organs is fully utilized.

	For more information about this strategy, please read the "Change Concept" document for the Organ Transplantation Breakthrough Collaborative. Click here to open this document.
Push	This is a strategy in the OTBC Change Package where organs are placed aggressively and strategically. The purposes of the Push Strategy are to: • Conduct an exhaustive and relentless search to identify a compatible recipient for every transplantable organ; • Organize to use exports and imports to assure high acceptance and transplantation rates; • Staff and standardize an increasingly effective placement process; and, • Use information and feedback to build trust and confidence in organ quality, information quality, and efficient matching. For more information about this strategy, please read the "Change Concept" document for the Organ Transplantation Breakthrough Collaborative. Click here to open this document.
Run Chart	A graphic representation of data over time, also known as a "time series graph" or "line graph." This type of data display is particularly effective for process improvement activities.
Standard Criteria Donor (SCD)	Donors after brain death (DBD) not meeting the OPTN expanded criteria definition.
Spread Strategy	"The process by which an innovation is communicated through certain channels over time among members of a social system," as defined by Everett Rogers (1995).
Strategy	An overarching description of how improvement can be achieved.
Target Hospitals for Spread	The hospitals within the DSA that are expected to adopt the new ideas and/or processes.
Test	A small-scale trial of a new approach or a new process. A test is designed to learn if the change results in improvement and to fine-tune the change to fit the organization and patients. Tests are carried out using one or more PDSA cycles.
Will	One of the key elements of breakthrough improvement. Improvement must be intended and have specific aims is crucial. The more specific the aim, the more likely the improvement.

References and Recommended Reading

Enlightened Leadership: (Ed Oakley & Doug Krug)

Good to Great: (Jim Collins)

Good to Great and the Social Sectors: A Monograph to Accompany Good to Great: (Jim Collins)

The Improvement Guide: (Langley, Nolan, Nola, Norman & Provost)

The Tipping Point: How Little Things Can Make a Big Difference: (Malcolm Gladwell)